STATUTORY INSTRUMENTS

2013 No. 1855

The Human Medicines (Amendment) Regulations 2013

PART 2

Amendment of the Human Medicines Regulations 2012

Insertion of regulations 256A to 256N

28. Immediately after regulation 256 (disqualification on conviction), insert—

"PART 12A

Sale of medicines to the public at a distance

Interpretation

256A. In this Part—

"common logo" means the common logo that is required to be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with the requirements laid down in the implementing acts adopted by the Commission under Article 85c(3)(**1**) of the 2001 Directive;

"information society services" means information society services as defined in Article 1(2) of Directive 98/34/EC(**2**) of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services;

"the list" means the list of persons who are entitled to supply medicinal products by information society services that is maintained on the website of the competent authority of a member State in which the person named on the list is established;

"relevant website of the member State" means a website of the competent authority of a member State providing information on—

(a) the national legislation applicable to the offering of medicinal products for sale at a distance to the public by information society services;

(b) the differences between member States regarding classification of medicinal products and the conditions for their supply;

(c) the purpose of the common logo;

(d) the list of persons offering medicinal products for sale at a distance by means of information society services as well as their website addresses;

(**1**) Article 85c was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).
(**2**) OJ No L 204, 21.7.98, p37; relevant amending instrument is Directive 1998/48/EC of the European Parliament and of the Council (OJ No L 217, 5.8.98, p18).

(e) background information about the risks related to medicinal products supplied illegally to the public by means of information society services;

(f) a hyperlink to the website of the EMA;

"website of the EMA" means the website of the EMA that—

(a) gives explicit information to the viewer on the relevant website of the member State containing information on persons authorised or entitled to supply medicinal products at a distance in that member State;

(b) provides information on the purpose of the common logo;

(c) provides background information about the risks related to medicinal products supplied illegally to the public by means of information society services;

(d) provides information on Community legislation applicable to falsified medicinal products;

(e) contains hyperlinks to the relevant website of the member State.

Person who may sell medicinal products by information society services

256B.—(1) A person may not sell a medicinal product at a distance to the public by means of information society services unless that person satisfies the following conditions.

(2) Condition A is that the person is included on the list of persons selling medicinal products at a distance that is published on the relevant website of the member State.

(3) Condition B is that the product to be sold by information society services is covered by an authorisation granted—

(a) under Regulation (EC) No 726/2004; or

(b) by a competent authority of the member State in which that product is destined to be sold.

(4) Condition C is that the person selling the medicinal product is authorised or entitled to sell to the public, including by information society services, medicinal products of that type or classification in the member State in which that person is established.

(5) Condition D is that where the sale is to a member of the public in the United Kingdom, it is in accordance with regulations 214 (sale or supply of prescription only medicines), 220 (sale or supply of medicinal products not subject to general sale) and 221 (sale or supply of medicinal products subject to general sale).

(6) Condition E is that the person selling the medicinal product has given a valid notification to the competent authority in a member State in which the person is established.

(7) Condition F is that the person selling medicinal products at a distance complies with the relevant provisions of the Electronic Commerce (EC Directive) Regulations 2002(**3**).

(8) A person has not given a valid notification for the purposes of paragraph (6) if—

(a) that person is not included on the list;

(b) the notification from that person is suspended by the competent authority of a member State; or

(c) the competent authority of a member State has been notified under regulation 256E(b) to remove that person from the list.

(**3**) S.I. 2002/2013.

Notification requirements for sellers of medicinal products at a distance

256C.—(1) The competent authority of a member State may not enter a person's details on the list unless it has been notified in accordance with paragraphs to (5).

(2) The notification must include—

(a) the name or corporate name of the person to be listed;

(b) information about—

(i) that person's permanent address from which the activity of selling medicinal products by information society services is to be carried out,

(ii) the commencement date of the activity of selling medicinal products by information society services,

(iii) the address of the website used for the purposes of selling medicinal products by information society services,

(iv) all relevant informantion necessary to identify the website, and

(v) information about the classification of all the medicinal products offered for sale at a distance.

(3) The notification shall—

(a) be in English; and

(b) unless paragraph (4) applies, in relation to the person whose details are to be entered on the list—

(i) be signed by that person, and

(ii) contain that person's telephone number and e-mail address if this is available.

(4) Where the notification is made by another person ("A") on behalf of the person whose details are to be entered on the list, the notification shall—

(a) contain the name and address of A;

(b) be signed by A; and

(c) contain the telephone number and e-mail address for A if this is available.

(5) The notification shall contain contact details for the site from which the activity of selling medicinal products by information society services is to be carried out including the—

(a) site address;

(b) name of person who may be contacted; and

(c) the telephone number and e-mail address of the person who may be contacted.

Procedure for listing persons who may supply medicinal products at a distance

256D.—(1) If the competent authority of a member State receives a notification under regulation 256C it must accept or refuse to include that person on the list within the period of 90 days beginning immediately after the day on which the notification is received by the authority.

(2) Paragraph (1) applies only if the requirements of regulation 256C(2) have been met.

(3) Before determining if a person can be included on the list, the competent authority of a member State may require the person giving the notification to provide such information as that competent authority thinks necessary, within the period specified by that competent authority.

(4) If a notice under paragraph (3) requires the person giving the notification to provide the competent authority of a member State with information, the information period is not to be counted for the purposes of paragraph (1).

(5) In paragraph (4), the "information period" means the period—

(a) beginning with the day on which the notice is given, and

(b) ending with the day on which—

(i) the competent authority of a member State receives the information; or

(ii) the person from whom the information is requested shows to the satisfaction of the competent authority of a member State that the information cannot be provided.

(6) The competent authority of a member State must give the person giving the notification a notice stating reasons for its decision in any case where—

(a) the competent authority of a member State refuses to include the person giving the notification on the list; or

(b) if the competent authority of a member State lists the person giving the notification otherwise that in accordance with the information supplied in the notification.

Removal of a person's entry from the list

256E. The competent authority of a member State may remove a person's entry from the list if—

(a) regulation 256I(1)(b) applies; or

(b) a notification to remove the entry is received from the person on the list.

Provision of information to the competent authority of a member State

256F.—(1) A person on the list must immediately inform the competent authority of a member State and, where applicable, the marketing authorisation holder, of medicinal products which that person—

(a) identifies as;

(b) knows or suspects; or

(c) has reasonable grounds for knowing or suspecting,

to be falsified.

(2) The person entered on the list must notify the competent authority of a member State of any change of circumstances which is material as regards that person's entry on the list.

(3) The competent authority of a member State may give a notice to a person on the list, requiring that person to provide information of a kind specified in the notice within the period specified in the notice.

(4) A notice under paragraph (3) may not be given to a person on the list unless it appears to the competent authority of a member State that it is necessary for that competent authority to consider whether that person's entry on the list should be varied, suspended or removed.

(5) A notice under paragraph (4) may specify information which the competent authority of a member State thinks necessary for considering whether the person's entry on the list should be varied, suspended or removed.

Grant or refusal to list a person

256G.—(1) On receipt of a notification from a person to be included in the list—

(a) the competent authority of a member State must include that person on the list if that person complies with the requirements in regulation 256C(2) to (5); or

(b) if it considers necessary or appropriate to do so, the competent authority of a member State must refuse to include that person on the list having had regard to—

(i) the provisions of these Regulations, and

(ii) any EU obligation.

(2) The competent authority of a member State must give a notice stating the reasons for its decision in any case where that competent authority—

(a) refuses to include a person on the list; or

(b) includes a person in the list otherwise than in accordance with the notification and that person requests a statement of its reasons.

(3) Where the competent authority of a member State decides to include a person on the list that competent authority must ensure that the relevant website of the member State includes—

(a) the name or corporate name of the person that is listed; and

(b) the person's website address in the United Kingdom.

Conditions to be met by a person entered on the list

256H.—(1) A person entered on the list shall not sell a medicinal product at a distance by information society services unless the following conditions are satisfied.

(2) Condition A is that the person entered on the list must comply with regulation 256B.

(3) Condition B is that without prejudice to the information requirements set out in Directive 2000/31/EC(**4**) of the European Parliament and of the Council on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, (Directive on electronic commerce), the website used to sell medicinal products at a distance must contain—

(a) the contact details of the competent authority of a member State which is responsible for maintaining the list on which the person selling products at a distance is included;

(b) a hyperlink to the relevant website of the Member State.

(4) Condition C is that without prejudice to any implementing Acts adopted by the Commission under Article 85c(3) of the 2001 Directive(**5**) the website used to sell medicinal products at a distance must contain the common logo which—

(a) is clearly displayed on every page of the listed person's website that relates to medicinal products offered for sale at a distance; and

(b) contains a hyperlink to the entry of that person in the list.

Power to suspend, vary or remove a person's entry on the list

256I.—(1) The competent authority of a member State may in accordance with regulation 256J—

(**4**) OJ No L 178, 13.7.2000, p1.
(**5**) Article 85c was inserted into Directive 2001/83/EC by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

(a) suspend a person's entry on the list for such period as the authority thinks fit;

(b) vary a person's entry on the list; or

(c) remove a person's entry from the list.

(2) The suspension of person from the list may be—

(a) total;

(b) limited to medicinal products of one or more descriptions; or

(c) limited to medicinal products sold at a distance from specified premises or a specified part of any premises.

(3) The power conferred by this regulation may only be exercised on one or more of the following grounds—

(a) in relation to any information notified to the competent authority of a member State under regulation 256C as a result of which the person was included in the list—

(i) the information so supplied was false or incomplete in a material respect,

(ii) a material change of circumstances has occurred in relation to any of the matters stated in the notification;

(b) the person on the list has materially contravened a condition required to be met by a person entered on the list under regulation 256H; or

(c) the person on the list has without reasonable excuse failed to supply information to the competent authority of a member State with respect to their notification when required to do so under regulation 256F(3).

Procedure where the competent authority of a member State proposes to suspend, vary or remove a person's entry on the list

256J.—(1) This regulation applies where—

(a) the provisions of regulation 256K do not apply; and

(b) the competent authority of a member State proposes to exercise the power in regulation 256I.

(2) The competent authority of a member State must notify the person on the list in writing of—

(a) its proposal;

(b) the reasons for it; and

(c) a specified date on which it is proposed that the suspension, variation or revocation should take effect.

(3) The specified date in paragraph (2)(c) must be no earlier than 28 days following the date of the notice given by the competent authority of a member State.

(4) The person to whom notice is given under paragraph (2) may before the date specified in the notice—

(a) make written representations to the competent authority of a member State with respect to the proposal; or

(b) notify the competent authority of a member State that the person wishes that competent authority to submit the proposal to review upon oral representations.

(5) If person on the list makes written representations in accordance with sub-paragraph (4)(a) the competent authority of a member State must take those representations into account before making a decision in the matter.

(6) If the person on the list gives notice of the proposal to review upon oral representation in accordance with paragraph (4)(b)—

(a) Schedule 5 has effect; and

(b) any reference to the licensing authority in Schedule 5 shall be read as a reference to the competent authority of a member State.

(7) If the competent authority of a member State proceeds to suspend, vary or remove a person's entry on the list in accordance with the provisions of regulation 256I it must give a notice to that person.

(8) The notice must—

(a) give particulars of the suspension, variation or removal; and

(b) give reasons for the decision to suspend, vary or remove the person's entry on the list.

(9) Paragraphs (7) and (8) are without prejudice to any requirement of Schedule 5 as to notification.

Suspension of a person's entry on the list in cases of urgency

256K.—(1) The competent authority of a member State may immediately suspend a person's entry on the list for a period not exceeding three months where it appears to that competent authority that in the interests of safety it is appropriate to do so.

(2) This paragraph applies where—

(a) a person's entry on the list has been suspended under paragraph (1); and

(b) it appears to the competent authority of a member State that it is necessary to consider whether the person's entry on the list should be—

(i) further suspended or varied, or

(ii) removed from the list.

(3) Where paragraph (2) applies, the competent authority of a member State must proceed as set out in regulation 256I (but this is subject to paragraph (4)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the competent authority of a member State proceeds as set out in regulation 256I and any proceedings under that regulation have not been finally disposed of before the end of the period for which the person's entry was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the competent authority of a member State to be necessary in the interests of safety to do so, the authority may further suspend the person's entry on the list for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 256I to suspend, vary or remove a person's entry on the list is made on an application under regulation 322(4) (validity of decisions and proceedings), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (interim order of the High Court).

Variation of a person's entry on the list on the application of that person

256L.—(1) This regulation applies if a person entered on the list applies to the competent authority of a member State for a variation of the person's entry on the list.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant; and

(d) be accompanied by such information as may be required to enable the competent authority of a member State to consider the application.

(3) The competent authority of a member State must vary a person's entry on the list or refuse to vary it within 30 days beginning with the day after the date when that competent authority receives the application.

(4) The competent authority of a member State may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the competent authority of a member State with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period—

(a) beginning with the day on which notice under paragraph (4) is given; and

(b) ending with the day on which the competent authority of a member State receives the information or the applicant shows to that competent authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 256I and 256K.

Offences: breach of regulations and false information

256M.—(1) A person is guilty of an offence if the person—

(a) contravenes regulation 256B(1); or

(b) offers medicinal products for sale at a distance otherwise than in accordance with the conditions in regulation 256H.

(2) A person is guilty of an offence if the person knowingly gives false information in—

(a) an application to be entered on the list in accordance with regulation 256C(2);

(b) an application for a variation in accordance with regulation 256L(2); or

(c) response to a notice under regulation 256L(4).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 256F(3) or 256L(4).

(4) A person is guilty of an offence if that person fails to inform the competent authority of a member State—

(a) of a falsified medicinal product in accordance with regulation 256F(1); or

(b) about a material change of circumstances in accordance with regulation 256F(2).

(5) It is a defence for a person charged with an offence under paragraph (4) to show that the person exercised all due diligence to avoid committing the offence.

Penalties

256N.—(1) A person guilty of an offence under regulation 256M(1), (2) or (4) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 256M(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale."